

JUN - 4 2004

Section 2 Summary

510(k) Summary of Safety and Effectiveness

Date: March 1, 2004

Submitter: GE Medical Systems *Information Technologies*
8200 West Tower Avenue
Milwaukee, WI 53223 USA

Contact Person: Diana M. Thorson
Regulatory Affairs Specialist
GE Medical Systems *Information Technologies*
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Device: Trade Name: Unity Network ID

Common/Usual Name: 21 CFR 870.2300 Monitor, Physiological, Patient

Classification Name:
21 CFR 870.2300 Monitor, Physiological, Patient (without arrhythmia detection or alarms)

Predicate Device: K033672 Unity Network ID

Device Description: The Unity Network ID system communicates patient data from sources other than GE Medical Systems *Information Technologies* equipment to a clinical information system, central station, and/or GE Medical Systems *Information Technologies* patient monitors.

The Unity Network ID acquires digital data from eight serial ports, converts the data to Unity Network protocols, and transmits the data over the monitoring network to a Unity Network device such as a patient monitor, clinical information system or central station.

Intended Use: The Unity Network ID is indicated for use in data collection and clinical information management through networks with independent bedside devices.

The Unity Network ID is not intended for monitoring purposes, nor is the Unity Network ID intended to control any of the clinical devices (independent bedside devices/ information systems) it is connected to.

Technology: The Unity Network ID employs the same functional technology as the predicate device.

Test Summary: The Unity Network ID complies with the voluntary standards as detailed in Section 9 of this submission. The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Testing on unit level (Module verification)
- Integration testing (System verification)
- Final acceptance testing (Validation)
- Performance testing
- Safety testing
- Environmental testing

Conclusion: The results of these measurements demonstrated that the Unity Network ID is as safe, as effective, and performs as well as the predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2004

Mr. Andrew Kluessendorf
Regulatory Affairs Specialist
GE Medical Systems Information Technologies
8200 West Tower Avenue
Milwaukee, WI 53223

Re: K040559
Trade/Device Name: Unity Network ID
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (including cardiometer and rate alarm)
Regulatory Class: Class II
Product Code: MWI
Dated: April 21, 2004
Received: May 11, 2004

Dear Mr. Kluessendorf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration

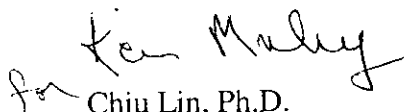
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and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

for Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

510(k) filed on March 1, 2004

Device Name: Unity Network ID

Indications For Use:

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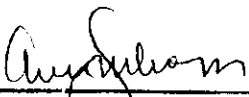
Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number: K040559